4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2020-D-1137, FDA-2020-D-1138, FDA-2020-D-0987]

Guidance Documents Related to Coronavirus Disease 2019; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of FDA guidance documents related to the Coronavirus Disease 2019 (COVID-19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the *Federal Register* of March 25, 2020, for making available to the public COVID-19-related guidances. The guidances identified in this notice address issues related to the COVID-19 PHE and have been issued in accordance with the process announced in the March 25, 2020, notice. The guidances have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidances is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be

posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the name of the guidance document that the comments address and the docket number for the guidance (see table 1). Received comments will be placed in the docket(s) and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy,

including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of these guidances to the address noted in table 1. Send two self-addressed adhesive labels to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911, or Erica Takai, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993-0002, 301-796-6353.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2020, as a result of confirmed cases of COVID-19, and after consultation with public health officials as necessary, the Secretary of Health and Human Services (HHS), pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247d), determined that a PHE exists and has existed since January 27, 2020, nationwide.[1] On March 13, 2020, there was a Presidential declaration that the COVID-19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020.[2]

In the *Federal Register* of March 25, 2020 (85 FR 16949) (the March 25, 2020, notice) (available at https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf), FDA announced procedures for making available FDA guidances related to the COVID-19 PHE. These procedures, which operate within FDA's established good guidance practices regulations, are intended to allow FDA to rapidly disseminate Agency recommendations and policies related to COVID-19 to industry, FDA staff, and other stakeholders. The March 25, 2020, notice stated that due to the need to act quickly and efficiently to respond to the COVID-19 PHE, FDA believes that prior public participation will not be feasible or appropriate before FDA implements COVID-19-related guidances. Therefore, FDA will issue COVID-19-related guidances for immediate implementation without prior public comment (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and § 10.115(g)(2)). The guidances are available on FDA's web pages entitled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders" (available at https://www.fda.gov/emergency-

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[1] Secretary of Health and Human Services, "Determination that a Public Health Emergency Exists" (originally issued on January 31, 2020, and subsequently renewed), available at: https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

[2] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (March 13, 2020), available at: https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/. On February 24, 2021, there was a Presidential Declaration continuing the national emergency concerning the COVID-19 pandemic beyond March 1, 2021. See Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Pandemic (February 24, 2021), available at https://www.federalregister.gov/documents/2021/02/26/2021-04173/continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic.

preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders) and "Search for FDA Guidance Documents" (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents).

The March 25, 2020, notice further stated that, in general, rather than publishing a separate NOA for each COVID-19-related guidance, FDA intends to publish periodically a consolidated NOA announcing the availability of certain COVID-19-related guidances that FDA issued during the relevant period, as included in table 1. This notice announces COVID-19-related guidances that are posted on FDA's website.

II. Availability of COVID-19-Related Guidance Documents

Pursuant to the process described in the March 25, 2020, notice, FDA is announcing the availability of the following COVID-19-related guidances:

Table 1.--Guidances Related to the COVID-19 Public Health Emergency

Docket No.	Center	Title of Guidance	Contact Information to Request Single Copies
FDA-2020-D-1137	CBER	Policy for Certain REMS Requirements During the Tocilizumab Shortage Related to the COVID-19 Public Health Emergency (December 2021)	Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, 1-800-835-4709 or 240-402-8010; email ocod@fda.hhs.gov.
FDA-2020-D-1138	CDRH	Enforcement Policy for Viral Transport Media During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised November 2021)	CDRH-Guidance@fda.hhs.gov. Please include the document number 20038-R2 and complete title of the guidance in the request.
FDA-2020-D-0987	CDRH	Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised November 2021)	CDRH-Guidance@fda.hhs.gov. Please include the document number 20010-R4 and complete title of the guidance in the request.

Although these guidances have been implemented immediately without prior comment, FDA will consider all comments received and revise the guidances as appropriate (see § 10.115(g)(3)).

These guidances are being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidances represent the current thinking of FDA. They do not

establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

A. CBER Guidance

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information (listed in table 2). Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

Table 2.--CBER Guidance and Collections

COVID-19 Guidance Title	CFR Cite Referenced in COVID-19 Guidance	Another Guidance Title Referenced in COVID-19 Guidance	OMB Control No(s).
Policy for Certain REMS Requirements During the Tocilizumab Shortage Related to the COVID-19 Public Health Emergency (December 2021)	21 CFR part 314 (New Drug Applications and Abbreviated New Drug Applications)		0910-0001
	21 CFR parts 210, 211 and 610 (Current Good Manufacturing Practices)		0910-0139
	21 CFR part 600 (Adverse Experience Reports)		0910-0308
	21 CFR part 601 (Biologic License Applications)		0910-0338

B. CDRH Guidances

The guidances listed below refer to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the table below (table 3). These guidances also contain a new collection of information not approved under a current collection. These new collections of information have been granted a public health emergency (PHE) waiver from the PRA by the Department of Health and Human

Services (HHS) on March 19, 2020, under section 319(f) of the PHS Act. Information concerning the PHE PRA waiver can be found on the HHS website at https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.

Table 3.--CDRH Guidances and Collections

COVID-19 Guidance Title	CFR Cite Referenced in COVID-19 Guidance	Another Guidance Referenced in COVID-19 Guidance	OMB Control No(s).	New Collection covered by PHE PRA Waiver
Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised November 2021) (document number 20038-R2)		Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders	0910-0595	
		Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization	0910-0607	
	800, 801, and 809		0910-0485	
	803		0910-0437	
	806		0910-0359	
	807, subparts A through D		0910-0625	
	807, subpart E		0910-0120	
	820		0910-0073	
	830 and 801.20		0910-0720	
				Manufacturer voluntary reporting to FDA of viral transport media manufacturing capacity information.
				Manufacturer voluntary reporting to FDA of sterile phosphate buffered saline/saline manufacturing capacity information.
Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised November 2021) (document number 20010-R4)				
		Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders	0910-0595	

		Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization	0910-0607	
	803	Medical Device Reporting	0910-0437	
				Confirmation to FDA that the developer of a diagnostic or serology test on FDA's notification lists and for which an Emergency Use Authorization (EUA) request was submitted, wants FDA to continue reviewing its EUA request.

IV. Electronic Access

Persons with access to the internet may obtain COVID-19-related guidances at:

- FDA web page entitled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," available at https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders;
- FDA web page entitled "Search for FDA Guidance Documents" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents; or
- https://www.regulations.gov.

Dated: January 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-01146 Filed: 1/20/2022 8:45 am; Publication Date: 1/21/2022]